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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,584	11/03/2005	Christophorus Joannes Lambertus Maria Meijer	2799/75219-PCT-US	2922
7590 Cooper & Dunham 1185 Avenue of the Americas New York, NY 10036				
05/16/2008				
EXAMINER				
SALIM, ALI REZA				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
05/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/551,584

**Applicant(s)**

MEIJER ET AL.

**Examiner**

A R. Salimi

**Art Unit**

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14, 16, 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 8/14/06 11/3/05

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group III (Claims 11-13, 15 and 17) in the reply filed on 04/16/2008 is acknowledged. The traversal is on the ground(s) that in the European counterpart application, the Examiner did not assert lack of unity of invention, and the examination of all Groups would not be unduly burdensome. This is not found persuasive because the decision's made by the European Examiner is not binding on this Office. The merit of requiring restriction among the Groups is still valid. Applicants have provided no evidence to establish why the requirement for restriction is improper. As stated previously teaching by Reeves et al shows the technical feature of Group I does not make a contribution over the prior art, and that argument still holds.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10, 14, 16, 18-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/16/2008.

**Applicants are reminded to cancel the claims to the non-elected Group(s).**

### ***Claim Rejections - 35 USC § 112***

Claims 11-13, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite for recitation of “target cellular component”, the intended metes and bounds of the said target component is not defined. This affects dependent claims 12-13, 15.

Claim 17 is vague and indefinite. The amendment file on 09/29/2005 has canceled the dependency. Yet the claim recites “according to...” Please clarify the dependency. The claim is confusing.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the intended or targeted cellular component. Is nucleic acid intended? This affects dependent claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Reeves et al (WO 02/14557 A1).

Reeves et al (WO 02/14557 A1) taught a method of detecting proliferative disorder cells, i.e. cancer in general, by detecting the tumor suppressor in lung cancer 1 (TSLC1) ( see the abstract, or claims 19-23, and 29-30). The Office has interpreted the limitation of proliferative

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disorder to cervical cancer, which is caused by human papillomavirus. The teaching and the claims of the above cited art anticipates the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-13, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Reeves et al (US Patent No. 6,596,493 B1).

Reeves et al taught a method of detecting proliferative disorder cells, i.e. cancer in general, by detecting the tumor suppressor in lung cancer 1 (TSLC1) ( see the abstract, and claims 4, 7-9). The Office has interpreted the limitation of proliferative disorder to read and include cervical cancer, which is caused by human papillomavirus. It is Office's position that Reeves et al by including the limitation cancer intended to capture patent protection for all types of cancer, including cervical cancer. The teaching and the claims of the above cited art anticipates the claimed invention.

Alternatively, under inherency doctrine where the claimed and prior art are identical or substantially identical processes, a prima facie case of either anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Moreover, there is no

requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See, Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). Applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002), wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not invented anything new. The Public was already in possession of the now claimed invention, whether or not Reeves et al had listed Human Papillomavirus as a cancer type. In other words, Applicants are not placing anything new in the Public Domain to be worthy of long term exclusive patent rights.

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/

Primary Examiner, Art Unit 1648

05/15/2008